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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/839,813      | 04/20/2001  | Robert Henry         | 54195-5001          | 3042             |

7590 07/09/2003  
MORGAN, LEWIS & BOCKIUS, L.L.P.  
1701 Market Street  
Philadelphia, PA 19103-2921

EXAMINER

BAUM, STUART F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 07/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/839,813

Applicant(s)

HENRY ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 32-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with application is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 & 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***RCE Acknowledgment***

1. The request filed on April 25, 2003 in paper no. 12 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 09/839813 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 22-42 are pending.

Claims 32-42 have been withdrawn from consideration because the claims are drawn to non-elected inventions.

2. Claims 22-31 are examined in the present office action.

### ***Specification***

3. The specification is objected to because all of the claimed priority is not stated. In the amendment filed 8/20/2002, Applicant amended the first line of the specification to include claimed priority to PCT Appln. No. PCT/AU99/00897 and Australian Provisional Appln. No. PJP6646. Applicants omitted Foreign Priority to Australian PCT Appln. No. PCT/US00/24244. Applicant should amend the first line of the specification (37 CFR 1.78) to indicate the claimed priority.

***Oath/Declaration***

4. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge that the present application is a continuation of PCT/AU99/00897 filed on 10/18/1999. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

***Priority Documents***

5. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Australia on 10/19/1999 and 10/22/1998. It is noted, however, that applicant has not filed a certified copy of the Australian applications as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25 and 28 and are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25 the metes and bounds of "high molecular weight" have not been defined. It is unclear what are the upper and lower limits delineating DNA that is considered "high molecular weight". In the amendment filed 8/20/2002, Applicants contend that this is an art recognized term and recite the text book, Plant Molecular Biology: A Laboratory Manual, which

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they contend they have incorporated by reference. The Office contends that even though this term is used in the art, the upper and lower limits delineating said DNA are not clear. In addition, the above cited text book was incorporated by reference in regards to subcloning (page 8, 3<sup>rd</sup> paragraph) and was not incorporated by reference in regards to defining "high molecular weight" DNA.

In claim 28, the metes and bounds of "a cereal" have not been defined. It is not clear from this expression which plants are included as the term has multiple meanings. Applicant is advised to specifically state the plants encompassed in the invention. Applicants contend (page 16 of the amendment filed 8/20/2002, 2<sup>nd</sup> full paragraph) that the term "cereal" is known in the art and is not considered indefinite. The Office contends that the term "cereal" has different meanings for different people. It is not clear exactly what plants are encompassed by the term "cereal".

### ***Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The inventors claim a recipient plant cell or tissue produced by a method of transferring DNA directly isolated from a donor plant into a plant cell or tissue comprising transforming a recipient plant cell by microprojectile bombardment. The Applicants do not identify or describe the directly isolated DNA that has been transformed into the recipient cell, the characteristic structural features inherent to said DNA nor the phenotype of the recipient cell. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of genetic and phenotypic description for the recipient plant cell, it remains unclear what features identify the recipient plant cell or tissue. Since the inventors have not described the genetics and phenotype of the newly transformed cells, the specification fails to provide an adequate written description to support the claimed material.

### ***35 USC 102/103 Rejection***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 31 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Turbin et al (1975, Mutation Research 27:59-68).

The claim is broadly drawn to any plant cell containing any "directly isolated" donor DNA which has not been characterized and which is not contained in a vector. Turbin et al teach barley cells and tissues which contain uncharacterized DNA directly isolated from other barley plants, not contained in a vector. The plant cells and tissues taught by the prior art differ from the claimed cells and tissues only in their method of manufacture, i.e. microprojectile bombardment. However, the claimed method of making the cells and plants would not confer a unique property to the resultant plants which would distinguish them from the prior art plants. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

9. Claims 22-25, 27, 28, 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said isolated DNA is not present in a vector and is high molecular weight DNA and a selection marker gene is present in a selection construct and wherein said donor plant and said recipient plant are members of different species or wherein both donor and recipient are cereal plants. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al teach a method of transforming a barley plant with directly isolated and uncharacterized genomic DNA isolated from another species of barley, which is a cereal plant and a plant produced by this method. The Office interprets said DNA to be high molecular weight DNA because both processes of isolating DNA produce long molecules of DNA.

Turbin et al do not teach transforming a plant using microprojectile bombardment wherein the plant is a species of *Oryza sativa* and incorporating a selection marker gene in a construct.

Christou teaches a method of transforming *Oryza* using microprojectile bombardment and transforming a plant with a selection marker gene that is present in a selection construct (page 201, sentence bridging left and right columns).

It would have been within the scope of one of ordinary skill in the art to modify the method of Turbin et al and to use the microprojectile bombardment method as taught by Christou. The motivation is taught by Christou who states that microprojectile bombardment is “the best method for achieving truly genotype-independent transformation” (page 198, right column, 1<sup>st</sup> paragraph).



Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

10. Claims 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turbin et al (1975, Mutation Research 27:59-68) in view of Christou (1997 Plant Molecular Biology 35:197-203) as applied to claims 22-25, 27, 28, 30-31 above, and further in view of Applicants' own admitted statement of the prior art (page 18, lines 17-18, Xiao et al 1996. Nature 384:223-) and Weining et al (1991 Theor. Appl. Genet. 82:209-216).

The claims are drawn to a method of transferring plant DNA into a plant cell comprising transforming a recipient plant cell or tissue by microprojectile bombardment with DNA directly isolated from a donor plant, wherein said isolated DNA is not present in a vector and is high molecular weight DNA and a selection marker gene is present in a selection construct and wherein said donor plant and said recipient plant are members of different species or different genera or wherein both donor and recipient are cereal plants and the donor plant is a species of *Zizania palustris*. The claims are also drawn to transforming a species of *Oryza sativa*.

Turbin et al in view of Christou teach a method of transforming a barley plant with directly isolated and uncharacterized high molecular weight genomic DNA isolated from another species of barley, which is a cereal plant and a plant produced by this method and a method of transforming *Oryza* using microprojectile bombardment and transforming a plant with a selection marker gene that is present in a selection construct.

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Turbin et al in view of Christou do not teach a donor plant and recipient plant from different genera nor where the donor plant is of the species *Zizania palustris*.

Applicants' admitted statement of the prior art teaches wild members of *Oryzae* have been shown to be important sources of genes for improvement of yield wherein *Zizania palustris* is a wild rice species.

Weining et al teach isolation of DNA from grasses and cereal plants.

Given the recognition of those of ordinary skill in the art of the value of producing a rice plant transformed with uncharacterized, high molecular DNA isolated from another species of rice plant and transformed by microprojectile bombardment as taught by Turbin et al in view of Christou, it would have been obvious to use the method of Turbin et al in view of Christou and to modify this method taught by Applicants' own admitted statement of the prior art by isolating DNA from the wild rice species, *Zizania palustris* as taught by Weining et al.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

11. No claims are allowed.

12. This is a RCE of applicant's earlier Application No. 09/839813. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in

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this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

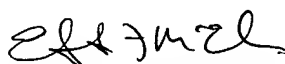
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

June 30, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600